The Medicines Patent Pool Adds New Sub-Licensing Agreements to Improve Access to Novel ARVs in Developing Countries

MPP signs sub-licences with six generic manufacturers for the development of Phase III drug Tenofovir Alafenamide

Geneva – 25 September 2014. Two months after signing a licence with Gilead Sciences, Inc. for the company's novel investigational medicine tenofovir alafenamide (TAF), MPP announced six new sub-licences with **Aurobindo**, **Cipla**, **Desano, Emcure**, **Hetero Labs** and **Laurus Labs** to allow generic manufacture of TAF for 112 developing countries. MPP's announcement comes one day after Gilead released positive results on two of its TAF Phase III studies, suggesting that the medicine has the potential to play a large role in the international community's efforts to scale-up HIV treatment.[1]

"The generic companies will begin development plans for a promising, new HIV product simultaneous with the US Food and Drug Administration's review to expedite access to low- and middle-income countries once the medicine is approved," said Greg Perry, Executive Director, MPP. "This is revolutionary in its approach to ensuring more people living with HIV have access to newer options for treating the disease."

In studies, TAF has demonstrated comparable antiviral efficacy to that of 300 milligram tenofovir disoproxil fumarate (TDF) – a World Health Organization-preferred HIV therapy – but at a dose that is 10 times lower. The smaller milligram dose may also allow lower production costs, as well as greater ease in developing new fixed-dose combinations and single tablet regimens.

"With this agreement Aurobindo will be collaborating with the MPP on seven HIV medicine development programmes," said Arvind Vasudeva, Chief Executive Officer, Formulations at Aurobindo. "We have finalized developments plans for key ARVs from our first sub-licence in 2011 and appreciate our continued role in providing promising new products such as TAF to low and middle-income countries in the future."

"Cipla is happy to sign its second agreement with MPP for TAF," said Subhanu Saxena, MD & Global CEO, Cipla Limited. "Cipla has been committed to the cause of HIV/AIDS for over two decades and this agreement emphasizes our ongoing commitment to provide advanced and effective treatments. This deal affirms Cipla's overarching goal of providing access to affordable medicines to patients using established mechanisms that allow us to put patients first."

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[1] The studies demonstrated that a single tablet regimen comprising elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and TAF 10 mg was non-inferior to Gilead's Stribild® (EVG/COBI/FTC/TDF at 300mg) based on the proportion of patients with viral load of less than 50 copies/ml at 48 weeks of therapy. In addition, EVG/COBI/FTC/TAF demonstrated more favourable renal and bone safety compared to Stribild.

"The Gilead-MPP licence paved the way for Chinese manufacturers to participate in the development of TAF and we look forward to working with the MPP on manufacturing processes," said Jinliang Li, Vice President of Desano. "We are the first Chinese enterprise to join the MPP as a sub-licensee, signing an agreement with the organisation just months ago for the manufacture of atazanavir (ATV) an important medicine for treating people who have developed resistance to their current regimens." Additionally Desano has also received a licence to produce generic TDF, emtricitabine and cobicistat.

"TAF is a pioneering new medicine potentially offering 'drug substance dose reduction' which could decrease side effects to the patient and enhance greater access of HIV medicines through possible cost benefits," said A.K. Khanna, Executive Director, Emcure Pharmaceuticals. "Working with MPP has been a pleasure."

"We consider our partnership with MPP to be crucial to the company's mission of bridging research and access, and are putting additional resources into ensuring more PLHIV have the medicines they need," said Bhavesh Shah, Director of International Marketing, Hetero Drugs Limited. "More than four million patients are currently taking Hetero Labs medicines and almost 50% are on TDF-based combinations, in part as a result of our 2012 sub-licence with the MPP." Hetero also signed a sub-licence with MPP for the development of dolutegravir, a promising new ARV recently approved by the European Medicines Agency.

"Laurus Labs is a long-time MPP partner," said C Satyanarayana, Chief Executive Officer. "We have been working closely with the team on six projects including the production of five Gilead ARVs from its licence with MPP in 2011. Laurus Labs looks forward to continuing this collaboration on TAF with a mutual goal of ensuring that, once registered, it is distributed rapidly across low- and middle-income countries."

In July, the MPP announced seven new sub-licences for the development of ATV and for DTG. With the agreements announced today, MPP will be managing 42 sub-licensing projects for the development of a range of ARVs for both children and adults.

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About the Medicines Patent Pool (MPP)

The Medicines Patent Pool is a United Nations-backed organisation founded in 2010 by UNITAID to increase access to HIV treatment and spur new innovation worldwide. The MPP offers a new public health approach to negotiating patent licences for the production of low-cost versions of new and existing medicines and works with manufacturers to encourage the development of needed new technologies such as fixed-dose combinations (FDCs) and formulations suitable for children. To date, MPP has signed agreements for nine antiretrovirals and for one medicine for an HIV opportunistic infection.

About Cipla Limited

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. For more than 70 years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 170 countries. Our portfolio includes 2000 products in 65 therapeutic categories with one quality standard globally. Cipla's turnover in 2013-14 was 1.7 billion USD.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognized globally for the pioneering role played in HIV/AIDS treatment as the first pharmaceutical company to provide a triple combination anti-retroviral (ARV) in Africa at less than one dollar a day and thereby treating many millions of patients since 2001.

Cipla's research and development focuses on developing innovative products and drug delivery systems and has given India and the world many 'firsts' for instance Triomune. In a tightly regulated environment, the company's manufacturing facilities have approvals from all the main regulators including USFDA, UKMHRA, WHO, MCC, ANVISA, and PMDA which means the company provides one universal standard both domestically and internationally.

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